Joint MPH Program

University of Gondar and Addis Continental Institute of Public Health

ASSESSMENT OF IMPLEMENTATION OF ISONIAZID PREVENTIVE THERAPY, ADHERENCE AND ITS DETERMINANTS IN PUBLIC HEALTH FACILITIES OF DIRE DAWA CITY ADMINISTRATION

By: Daniel Taddesse

Advisors: Prof. Yigzaw Kebede

Prof. Yemane Berhane

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Abbreviations

ACIPH	Addis Continental Institute of Public Health
AFB	Acid Fast Bacilli
ANC	Antenatal Clinic
ART	Antiretroviral therapy
ARV	Antiretroviral
CI	Confidence interval
CXR	Chest X-Ray
DDHB	Dire Dawa city administration health bureau
ETB	Ethiopian Birr
FHAPCO	Federal HIV/AIDS Prevention and Control Office
FHC	Facility HIV Committee
FMOH	Federal Ministry of Health
HC	Health Centre
HCT	HIV counseling and testing
HIV	Human immunodeficiency virus
HMIS	Health Management Information System
IC	Infection control
ICF	Intensified case finding
INH	Isoniazid
INRUD IAA	INRUD Initiative on Adherence for Antiretroviral
INRUD	International network for rational use of drugs

IPT	Isoniazid preventive therapy
PT	Preventive Therapy
MDT	Multi-Disciplinary Team
MSH	Management Sciences for Health
OPD	Out Patient Department
OR	Odds ratio
PI	Principal Investigator
PLHIV	People living with HIV
PMTCT	Prevention of mother to child transmission
PT	Preventive therapy
TB	Tuberculosis
UoG	University of Gondar
WHO	World Health Organization
GAMET	Global HIV/AIDS Monitoring and Evaluation Team
PIHCT	Provider Initiated HIV Counseling and Testing

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Abstract

Background: Scientific information on the number of IPT beneficiaries, their rate of adherence vis-à-vis determinants of adherence is scarce in Ethiopia. Hence, it was practically impossible to discuss whether the preventive therapy was reaching those who were in need of the service or whether it was being rationally used.

Objective: The main objective of the study was to assess the implementation of IPT, adherence to the treatment and its determinants.

Methods: This cross-sectional study was conducted in five ART service providing public health facilities of Dire Dawa City Administration from April to May, 2009. Primary data was collected through patient exit interviews of 238 PLHIV who were on IPT and in-depth interview of 4 health service managers, while secondary data was collected from health facilities through observation. SPSS V.16 was used for data anlysis. Descriptive statistics was generated for socio-demographic and other quantitative data while thematic analysis was conducted for qualitative data. Binary logistic regression tests were performed to analyze the degree of association between the dependent and the independent variables. Odds ratio was determined using cross-tabulation on respondents' age and sex to analyze association with adherence level.

Results: In general, health facilities' organizational capacity was assessed to be good whereas there were observed differences among the facilities in patient load and service availability. However, IPT service coverage and adherence level were generally low in the studied health facilities with only 179 (37.3%) individuals receiving INH among the eligible 480 with aggregated treatment adherence level of respondents being 84.8% and self-reported full adherence level being 78.2%. Being away from home, forgetfulness and running out of pills were identified as the major reasons for missing INH doses, which implies that the most important factors for adherence were usually those that are related to the patients themselves; and contributions of health service and community level factors to non-adherence were minimal. Socio-demographic and patient care variables were not found to have significant association with the level of adherence.

Conclusion and recommendations: Attitude and follow-up were found to be the main challenges for better service utilization and appropriate adherence. Therefore, improving attitude, strengthening service provision follow up, designing and implementing appropriate strategies that strengthen adherence counseling and patients follow up are recommended.

1. Introduction

1.1. Background

The Human Immunodeficiency Virus (HIV) pandemic brought about a great challenge to the TB prevention and control Program. It has been found that latent TB infection in HIV-positive individuals reactivates at a rate of 10% per year as opposed to 5%-10% over a life time risk for HIV-negative individuals (1). According to the World Health Organization (WHO), out of the total of 9.3 million incident cases of TB, there were 1.4 million new HIV-positive TB cases in 2007. The African Region accounts for 79% of estimated HIV-positive TB cases; most of the remaining cases are in South-East Asia Region (2).

To reduce the burden of TB in HIV infected individuals, TB preventive therapy was first recommended by WHO and UNAIDS in 1998 along with other key interventions. Preventive therapy for TB is safe and efficacious and is recommended for all PLHIV living in areas with a prevalence of latent TB infection >30%, and for all PLHIV with documented latent TB infection or exposure to an infectious TB case, regardless of where they live. Subsequently, in 2004, WHO incorporated the Isoniazid preventive therapy (IPT) as one of the twelve key TB/HIV collaborative activities to reduce the huge impact of the co-infection (3). The requirements for the implementation of preventive therapy included adequate HIV counseling, sufficient trained health-care providers, linkage of HIV-care and TB-control services, and TB treatment services that have a high probability of curing cases of TB (4).

Many national TB and HIV programs, however, had chosen not to implement the policy. HIV care programs had instead focused efforts on the logistics of scaling up the life saving intervention of antiretroviral therapy (ART) at the expense of implementing other interventions such as preventive therapy. Other concerns about preventive therapy had also contributed to its low uptake, including difficulties in ruling out active TB before starting, the risk of producing INH-resistant TB, and toxicity of INH, especially in combination with antiretrovirals (ARVs). As a result, only 0.06% of PLHIV worldwide were given TB preventive therapy in 2005 (5). In 2007, the proportion of estimated number of HIV-positive people who received IPT among the eligible ones increased to 0.2% globally and 0.1% for Africa (2).

The other issue associated with IPT was the high rate of defaulters observed in different countries; some studies revealed that the defaulter rate could go as high as 37% (6). Despite the fact that compliance is one of the factors that determines the success of the preventive therapy, studies conducted in different places documented poor adherence. For instance a study in South Africa reported 28% non-adherence while in America it was reported to be 17.8% (7,8). Another study in Thailand documented 32.5% non-adherence rate for IPT among HIV infected individuals in Chiang Rai province (9).

Like the rest of the world, the HIV pandemic presented a massive challenge to the control of tuberculosis (TB) in Ethiopia. Routine data collected from health facilities indicated 41% and 31% co-infection rates in the years 2005/6 and 2006/7, respectively (1). For 2007, WHO estimated that 19% of new TB cases in Ethiopia were HIV-positive (2). Besides the synergistic health consequences, the dual infections have a number of impacts on the health system that

resulted from huge demand for health services. Cognizant of this fact, the national TB and HIV prevention and control programs designed and implemented a collaborative strategy in May 2004 that aimed at prevention of HIV and prevention and control of TB, which ultimately would reduce the burden of both infections (10). The collaborative work was initiated as a pilot project in six hospitals and three health centers to expand to more than 330 health facilities by 2008 (11).The national TB/HIV collaboration adopted the twelve, WHO recommended collaborative activities of which Isoniazid Preventive Therapy (IPT) was one.

1.2. Rationale

IPT was incorporated as one of the activities in the national *Implementation guidelines for TB/HIV collaborative activities in Ethiopia* only in 2008. But, there were many reasons to believe that it had been implemented at some health facilities of the country since 2005. So far, there are no studies in the country that assessed the implementation of IPT and the rate of adherence to the therapy. Moreover, reasons for non-compliance and the possible determinants of adherence have not been studied in Ethiopia. Though it is difficult to get a complete report, however, the number of individuals who benefited from IPT was reported to be low throughout the nation. This makes it practically impossible to discuss whether the preventive therapy had reached those who were in need of the service or whether INH was being rationally used.

This information gap made it impossible to plan and implement appropriate interventions with regards to expanding the service and improving adherence. This study is, therefore, aimed at providing information that would help for future programmatic decisions with regards to expanding the use of IPT and improving adherence.

2. Literature review

2.1. Global and national TB/HIV burden

HIV is the primary reason for failure to meet tuberculosis (TB) control targets in settings with a high prevalence of HIV infection. Although sub-Saharan Africa bears the brunt of the HIV-fuelled TB epidemic, TB is a major cause of death among people living with HIV/AIDS worldwide (12). If one looks at the HIV prevalence among new TB cases globally, 1.37 million (14.8%) of 9.27 million incident cases of TB in 2007 were HIV positive. Of these co-infection cases, the African Region accounted for 79 % followed by South-East Asia Region with 11% of cases. For Ethiopia, the reported figure was 19% for the same year (2).

2.2. Impacts of TB/HIV

The synergy between TB and HIV/AIDS is strong: TB is a leading cause of morbidity and mortality, and HIV is driving the tuberculosis epidemic in many countries. HIV increases susceptibility to infection with *Mycobacterium tuberculosis*, the risk of progression to TB disease, and the likelihood of re-infections and relapses (1). On the other hand, TB is often the first and most common opportunistic infection in HIV infected individuals resulting in disease progression and mortality. For instance, WHO estimates that 230,000 people living with HIV would have died as a result of TB in 2008 only; this is around 630 persons per day despite the fact that TB is curable and possibly preventable (13).

2.3. TB/HIV collaboration

In 2004, WHO issued a policy on TB/HIV Collaborative Activities to accelerate implementation of the twelve recommended activities that reduce the TB and HIV co-epidemic. These recommendations were categorized under three major objectives: establishment of mechanisms for collaboration between TB and HIV control programs, reducing the burden of TB in people living with HIV and reducing the burden of HIV in people infected with TB (5). The so called *Three I's* strategy was selected by WHO and collaborative partners to achieve the second goal, which aimed at reducing the burden of TB in PLHIV. The *Three I's* are: intensified case finding (ICF), Isoniazid preventive therapy (IPT) and TB infection control (IC) (13).

Although global consensus had been achieved around an interim policy on TB/HIV, the wide dissemination of the policy was not satisfactory, and implementation of joint TB/HIV activities had not been scaled up till 2005 (12). In 2006, however, the number of countries implementing collaborative TB/HIV activities and related services significantly increased to 112, from just 7 countries in 2003 (14). Ethiopia has been part of this global effort since 2004, when the national TB/HIV collaborative activities strategy was developed and implemented.

2.4. Isoniazid preventive therapy

Preventive therapy (PT) against TB is the use of one or more anti-TB drugs given to individuals with latent Mycobacterium tuberculosis infection in order to prevent the progression to active disease. HIV is known to be the most powerful risk factor for progression from latent infection to active disease. While non-immunocompromised persons with latent infection have about 5% chance of developing active TB later in life, the chance rises to 50% in HIV-infected individuals.

In high TB prevalence countries, between 2.4% to 7.5% of HIV-infected adults may develop active TB each year (6).

The efficacy of PT in the prevention of the progression to active TB in HIV-infected persons is supported by a number of researches. In one randomized clinical trial, it was reported that IPT reduces the risk of developing active TB significantly with additional advantage of delaying disease progression and death in HIV-infected individuals (15). One other study in Thailand documented that randomized trials administering Isoniazid for 6 months and 12 months duration have shown a significant decrease of TB incidence in tuberculin skin test positive persons compared to those who took placebo. IPT for tuberculin skin test positive persons living in areas with high TB prevalence will reduce the risk of developing active TB in short term to around 40% of what it would have been without such treatment (6). In one other review, 11 trials were included with a total of 8,130 randomized participants and preventive therapy (any anti-TB drug) versus placebo was associated with a lower incidence of active tuberculosis (RR 0.64, 95% CI 0.51 to 0.81) (16). In one WHO document, it was stated that a meta-analysis showed an overall efficacy of 64% in tuberculin positive individuals while in populations from high burden areas with a mix of tuberculin-positive and negative individuals the overall efficacy was 33%. A morbidity and mortality weekly report of CDC documented that IPT has 95% efficacy among infected individuals who have completed the treatment (17).

Isoniazid preventive therapy has not been extensively studied in HIV-infected children. In one placebo-controlled randomized trial, INH dosed at 10 mg/kg orally once daily or three times weekly was associated with a 53 percent reduction in mortality. The survival benefit occurred early (within 50 days) and was apparent in all CDC HIV categories of disease. Although the

results were preliminary and the population studied lived in the Western Cape Province of South Africa, a region with one of the highest incidence rates of TB worldwide (4.1 percent annualized risk for children), they made a strong case for offering Isoniazid preventive therapy to HIV infected children living in other countries with high TB prevalence (18).In another small, randomized trial, INH preventive therapy was shown to reduce early mortality by 50% in children living with HIV (19).

With regards to efficacy of secondary prophylaxis, treatment of latent TB in those who have already been treated for active TB, a study in South Africa reported a 55% reduction in the incidence of recurrent TB among men who received IPT compared with those who did not (7). However, a recent WHO document indicated that secondary preventive therapy was not recommended, though several trials and cohort studies suggested possible benefit (19).

In summary, many literatures indicate that TB preventive therapy is safe and effective in PLHIV, reducing the risk of TB significantly. As per WHO guidelines, IPT is efficacious and is recommended for all people living with HIV in countries where tuberculosis is common and in all those with documented co-infection, regardless of where they live. The recommended dose of INH for TB preventive therapy in adolescents and adults living with HIV is 300 mg daily for nine months, with six months being an acceptable alternative. Isoniazid 800-900 mg twice weekly is an effective and well tolerated alternative regimen that can be offered where treatment supervision is feasible. For children, Isoniazid 5 mg/kg for nine months is the recommended regimen (20).

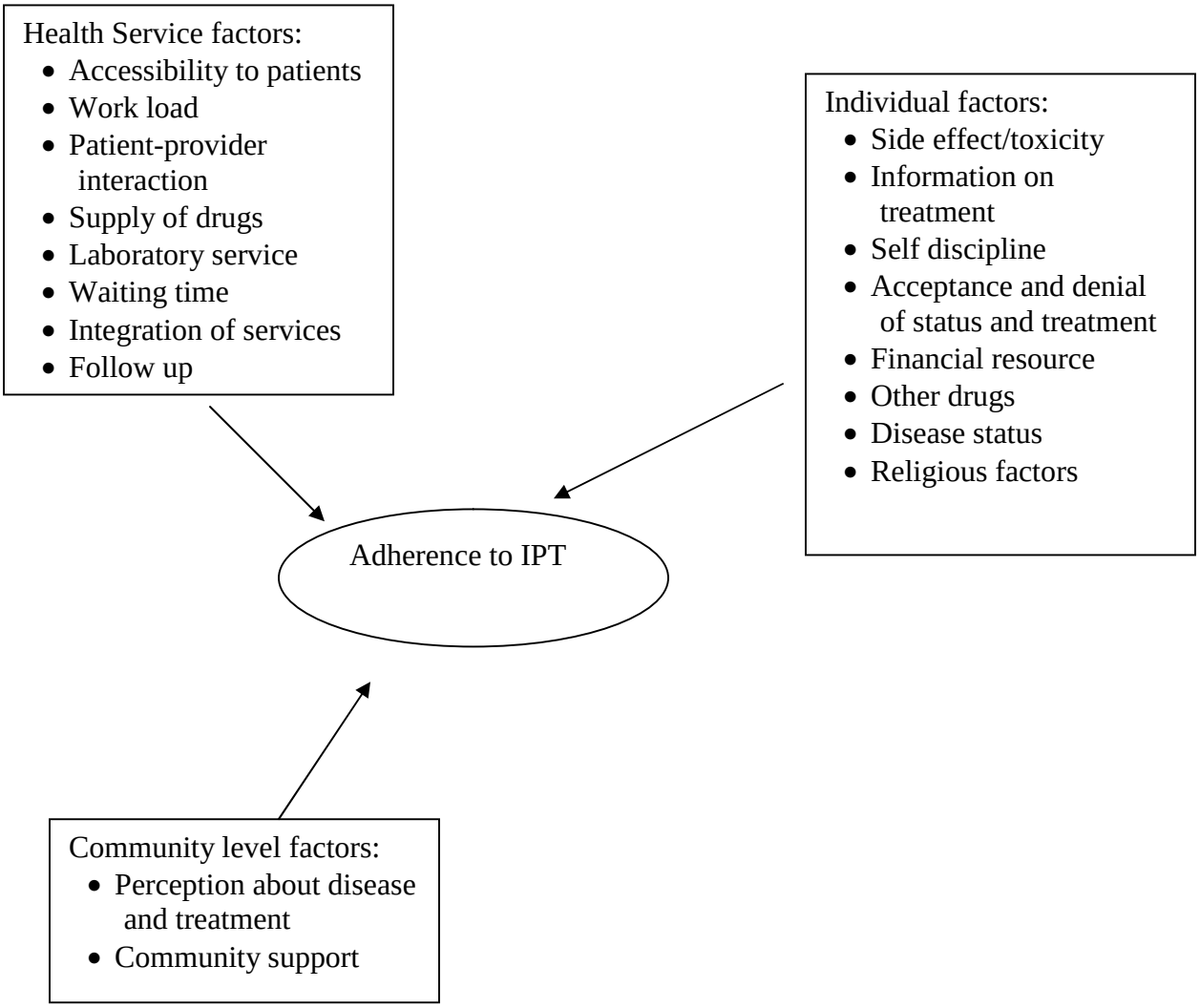
2.5. Issues in INH Preventive Therapy

Despite the strong recommendation by WHO, implementation of IPT had been reported to be very low in a number of documents (10, 19). Only 25,000 (0.06%) people living with HIV worldwide were reported to have received it in 2005. In 2007, only 29 countries had policies related to IPT (2). Though securing sufficient amount of fund for effective implementation of IPT was forwarded as the main reason of failure, it is evident that reluctance to its implementation is driven primarily for technical and logistical difficulties of excluding active TB and fear of development of drug resistance. However, except one review of literatures that indicated an increased risk for INH-resistant TB (21), many of the documents reviewed did not provide any evidence of resistance development due to IPT.

Adherence to INH preventive therapy is an important issue, and interventions to promote adherence may be very useful (19). A controlled trial cited *Healthy People 2010* for calling for 90% of LTBI patients to complete treatment (22). However, the same study reported an observed treatment completion rate as low as 5% among adults and 50% among adolescents. A feasibility studies on 9 months daily self-administered INH in one regional hospital in Thailand established that the process of targeting appropriate groups (e.g. excluding active TB), delivering preventive therapy and achieving adherence, was complex. In addition, data collected from 26 hospitals in the Northern part of Thailand found out that the defaulter rate was as high as 37%. The study also showed that defaulter rate increased over time. The possible determinants the study identified for low level of adherence were weak service integration and inadequate pre and post treatment counseling (6).

In all the literatures reviewed, there was no agreed figure mentioned as an acceptable level of adherence to IPT. A review of adherence studies for chronic illnesses found that achieving adherence rates above 80 percent is difficult, even in resource-rich countries (23). Various incentives and enablers have been known to improve adherence in diverse populations of people receiving IPT (19). Based on the findings from different literatures and taking the local situation and context in to consideration, a simple conceptual framework was developed to help understand the relationship of the different factors with adherence (Figure 1). However, the fact is that the interactions might be more complex than described below.

Figure 1 Conceptual framework relating adherence to IPT with different factors



In Ethiopia, IPT has been incorporated in the 2008 national 'Implementation Guidelines for TB/HIV Collaborative Activities in Ethiopia' and is being implemented throughout the country. But, at central level, it was difficult to get a comprehensive report on the IPT service utilization coverage. During the literature review, no documented study was found that measured the prevalence of IPT and adherence in Ethiopia. Yet, in the national guideline, five practical barriers to IPT use were pointed out: fear of resistance development, fear of side effect, fear of re-infection, attitude and follow-up. Some other operational factors such as organization of the services and availability of drugs were not indicated as possible challenges.

In general, there is a huge information gap with regards to IPT implementation in the country. Macro level and individual factors that affect IPT use and adherence were not documented.

3. Objectives

3.1. General objective:

- The main objective of the study was to assess the implementation of Isoniazid Preventive Therapy (IPT), adherence to the treatment and its determinants in the public health facilities of Dire Dawa City Administration.

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3.2. Specific objectives:

- To assess health facilities organizational capacity in terms of IPT service provision;
- To determine the prevalence of IPT among eligible PLHIV;
- To measure the degree of adherence to IPT;
- To identify reasons for non-adherence and factors that affect adherence to IPT.

4. Study methodology

4.1. Study area

The study was conducted in Dire Dawa city administration, which is located 520 Km away from the capital Addis Ababa in the Eastern part of the country with an estimated population size of 371,000. Administratively, Dire Dawa is divided in to 9 urban kebeles and 32 peasant associations. The city administration has a total of 50 public health facilities comprised of one hospital, 12 health centers and 37 health posts. Currently, there are six health facilities in Dire Dawa that are providing ART service including one private hospital. According to the FHAPCO's Tahisas, 2001 E.C. (December, 2008) report, the ever enrolled number of HIV-positive individuals was 5466 for Dire Dawa.

Dire Dawa was purposely selected for the reason that there were evidences of better IPT service coverage in Dire Dawa as compared to other parts of the country, satisfying the necessary condition for adherence assessment. Accordingly, all the five public facilities that were providing the service were covered in the study.

All the covered five public health facilities were located in Dire Dawa town except one which was 9 KMs away. The only hospital in Dire Dawa, Dil Chora, is the oldest of all facilities that has served for more than 50 years while the rest are relatively younger. Unlike the health centers, which were mostly serving Dire Dawa's population, Dil Chora referral hospital provided its services to patients from the neighboring regions (Afar, Somali, Oromia, Harari) and sometimes from neighboring countries (Somalia and Djibouti).

4.2. Study design

The study employed both qualitative and cross-sectional quantitative designs and was conducted from March to June, 2009. In-depth interviews were conducted with facility managers to gather qualitative data with regards to service availability and efficiency while additional data was collected by observation and document review. Data on adherence rate (outcome variable) and its possible determinants (independent variables) was collected through patient exit-interview at one point in time.

4.3. Study population

The study population consisted of PLHIV, who were enrolled for chronic HIV care and already on IPT by the time of visit, heads of facilities and service providers. For the patient exit interview, the participant IPT clients were only those who were at least 18 years old by the time of data collection. For the prevalence study, patient records of those patients who were enrolled for HIV chronic care in the previos five months (November 14, 2008 to April 12, 2009) were reviewed. This period was selected because of the fact that IPT service was restarted only starting November 14, 2009 when the drug was made available after over one year of supply interruption. Those patients with incomplete information in their records, children < 14 years of age for whom TB screening is difficult, and pregnant women for whom IPT is not recommended were excluded from the prevalence study.

4.4. Variables

4.4.1. Dependent variable

The dependent variable was level of adherence to IPT.

4.4.2. Independent variables

The independent variables were age, sex, level of education, patient status and patient care indicators (travel time, waiting time, cost of transport and proper labeling of drugs).

4.5. Sample size determination and sampling procedure

Applying a finite population correction formula, with 95%CI, 5% margin of error, P=0.5, and N=625 resulted in a sample size of 238; adding 10% additions for non-response made the total sample size 261 (where P refers to the expected adherence level and N is the total number of patients who were on IPT). The value of P is taken as 0.5 (50%) because there is no documented estimate of adherence rate to IPT in Dire Dawa. The calculated sample size and the actual number of data analyzed are presented in Table 1 disaggregated by health facility.

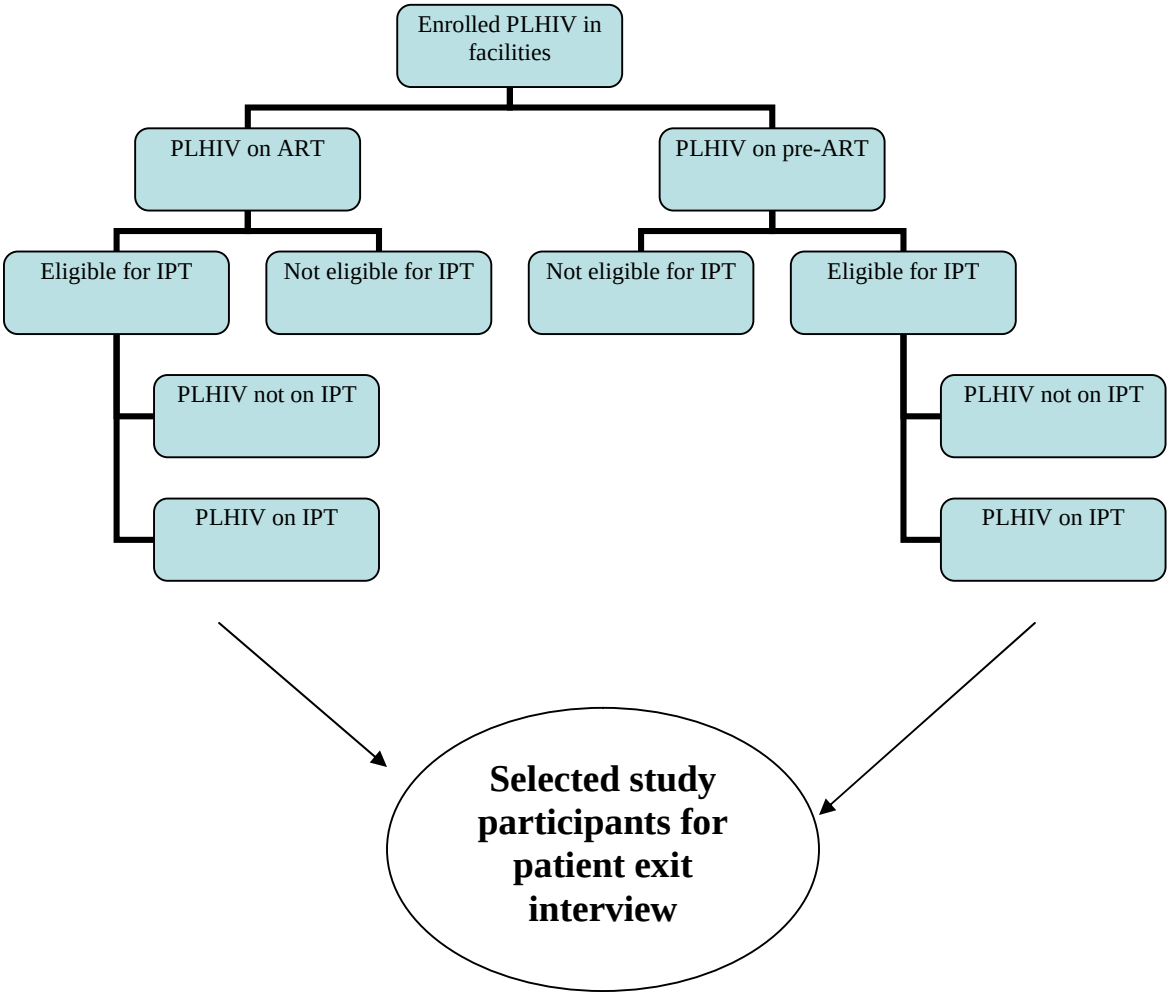
Table 1 Sample size determination for patient exit interview

Name of health facility	Total # PLHIV on IPT	% PLHIV on IPT	Sample size/Weighted sample	Actual # of data analyzed
Dil Chora hospital	384	61.4	160	144
Sbian HC	108	17.2	45	41
Dire Dawa HC	77	12.3	32	31
Melka Jebdu HC	8	1.3	3	3
Legehare HC	48	7.7	20	19
Total	**625**	**100**	**260**	**238**

For the exit interview, since patients come to facilities only on a monthly basis, it would take a very long time to interview the required number of patients if random sampling is applied.

Accordingly, to accommodate for the time limitation, consecutive patients who were HIV positive and prescribed with INH were invited to participate in the completion of the questionnaire that was done by trained health professionals (Figure 2).

Figure 2 Sampling procedure for patient exit interview



A total of 251 interviews were conducted of which 238 (94.82%) were selected for analysis after filtering those with inconsistent and missing information; this was at an average of 48 interviews per facility. The numbers of interviews vary greatly among the facilities with the minimum of 3 and the maximum of 144.

To gather information with regards to service provision and facility organization, in-depth interview and facility observation techniques were employed in four of the five facilities including one hospital and three health centers (Table 2). In depth interview was conducted to collect information from facility managers, while additional information were gathered from professionals including staff of the ART clinic, TB clinic, pharmacy, and laboratory. For specific quantitative information, relevant secondary data were also consulted including patient records, laboratory ledgers and pharmacy records.

Table 2 Names of visited health facilities and type of data collected

Names of facilities	Type of facility*	Type of data collected		
		Facility Observation (Y/N)	In-depth interview (Y/N)	Patient exit interview (Y/N)
Dil Chora	Referral hospital	Y	Y	Y
Sabian	Type A health center	Y	Y	Y
Legehare	Type A health center	Y	Y	Y
Melka Jebdu	Type A health center	Y	Y	Y
Dire Dawa	Type A health center	N**	N	Y

* All are public health facilities

** Data on IPT service was collected through document review

To determine the prevalence of IPT, data was collected from records of patients who were enrolled during the past 5 months from the initial day of data collection (November 14, 2008 to April 12, 2009). The period was chosen for the reason that INH was continuously available only from November, 2008 onwards. If data was collected for the duration including the time that the

drug was unavailable, the results would be biased since unavailability of the drug affect the prescription pattern (initiation of IPT).

4.6. Data collection Period

The pre-test, training and data collection were conducted from April 8 to May 22, 2009. During the first two weeks, data was collected from health service providers and different secondary data sources. Patient exit interviews were undertaken in six weeks time; originally, it was planned to finalize this activity in three weeks time assuming that sufficient number of participants would turn out.

4.7. Data collection instruments

The study employed three types of data collection instruments, which are attached as Annex II. All the data collection tools were amended from the INRUD-IAA project that is developed by Management Sciences for Health (MSH), Karolinska Institute, Harvard University, and the World Health Organization (WHO) in collaboration with INRUD groups in Ethiopia, Kenya, Rwanda, Tanzania, and Uganda (23).

The first tool was a semi-structured questionnaire (Tool 1), which was used for in-depth interview with the heads of the health facilities with issues focusing on organizational capacity, service provision, integration of services and IPT implementation. This activity was performed to understand the general situation of the service and to gather realistic recommendations as seen from managerial level.

The second instrument was a checklist (Tool 2), which was used to collect data on facility organization, service provision and prevalence of IPT among eligible individuals. Data was collected from different units of the health facility primarily through observation and document review. Brief discussions were also held with relevant staff whenever required.

The patient exit interview instrument (Tool 3) is a structured questionnaire, which was used to collect data on adherence from IPT clients. This tool was used to collect information on socio-demographic characteristics of patients and rate of adherence to IPT. The reasons for non-adherence and other relevant information were also gathered from the study participants.

Before the actual data collection, the instruments were field-tested in Dil Chora hospital of Dire Dawa city administration by the principal investigator. The field test was planned to assess the logical flow of the questions, understanding by respondents, missed points and other relevant issues. Based on the findings of the pre-test, the instruments were finalized and duplicated for use. Dil Chora hospital was also included in the actual study but this time data was collected from different study participants by trained health professionals.

4.8. Data collectors

The data collectors were health professionals, composed of nurses and pharmacy professionals, who were working in health facilities of Dire Dawa city administration. These professionals were selected based on the fact that they were familiar to the health services and that they could stay there as long as it took to collect data from patients; this was taking the limited time and cost that was available for the study. Moreover, since they were working in the study facilities, it was easy

to get information on those patients who were on IPT among which study subjects were selected, which would have otherwise been difficult had other data collectors were recruited. Prior to data collection, they received a two days training on how to complete the tools that included practical data collection simulation sessions. The principal investigator and one additional supervisor supervised the data collection process and provided on-site advice as required. The additional supervisor was a senior health professional from the Dire Dawa health bureau, who was working as a focal person for TB/HIV activities in Dire Dawa city administration. All in-depth interviews were conducted by the principal investigator.

4.9. Data entry and analysis

Data collected by the instruments were edited and checked for missing items and consistency in the field. Prior to data entry data were edited and post-coded for computerization. One employed data clerk and the principal investigator entered the data in to the computer and the data were cross-checked for error. SPSS version 16.0 was used for analysis. Univariate analysis was performed and descriptive statistics were generated for the overall socio-demographic characteristics of the population and patient care indicators. Binary logistic regression tests were conducted to assess the association of independent and dependent variables at 0.05 level of significance. For analysis purpose age, transport cost, travel time and waiting times were categorized in to groups.

Qualitative data regarding facility organization and service provision were analyzed thematically and summaries of the findings were documented. Similarities and differences among the health

facilities were critically weighed and presented. In this report, qualitative and quantitative data are presented in such a way they complement each other.

4.10. Ethical consideration

Approval of ethical clearance was secured from Ethical Clearance Committee of the School of Public Health, University of Gondar. In response to a written letter of request for cooperation from the ACIPH management, a written permission was secured from Dire Dawa City Administration Health Bureau.

Data collectors were trained on how to handle sensitive and emotional issues and on the importance of keeping confidentiality. A designed consent form (Annex I) was used to obtain study subjects' agreement to participate in the study, following an explanation about the purpose of the study and what is expected of them. Names and any other sensitive personal information of individual study subjects were not recorded during data collection and assurance of confidentiality was provided prior to interview. Furthermore, data collectors who were not directly involved in ART and IPT service provision were chosen for this study. Only authorized people had access to raw data collected from the field. The final study report shall be disseminated to Dire Dawa City Administration health bureau, all the visited health facilities, Federal Ministry of Health and MSH-Ethiopia office.

4.11. Operational definitions

The following words/terms were used in this study with their corresponding operational definitions.

Prevalence of IPT: The prevalence of IPT is the proportion of those eligible PLHIV who received the preventive therapy. It is determined by dividing the number of individuals who received IPT by the total number of individuals enrolled for HIV care and who were eligible for the treatment in a specified period of time.

Complete adherence: An individual is said to completely adhere to IPT if s/he took all the prescribed doses for specified period of time. Thus, complete adherence is the proportion of individuals who reportedly took all the seven doses of INH in the past seven days.

Adherence rate: For this study, adherence rate is expressed as the proportion of those individuals who reportedly took at least 85% of the prescribed doses of INH during the past seven days.

Proper labeling: A drug is said to be properly labeled if the label contains at least the following information: drug name, strength, dose and dose per day.

Patient knowledge: A patient is said to know how to take the medicine if s/he is able to tell the name of the drug and the number of doses to take per day.

5. Results

5.1. Results of facility observation and in-depth interviews

On average, 3 professionals work full time (week days) in the ART clinics (Facility range: 2 - 4), with main responsibilities of providing comprehensive HIV care services. All the four ART clinics were open for 39 hours per week (8 hours per day Monday through Thursday and 7 hours on Fridays) while two facilities were open on Saturdays for 4 hours. The mean daily patient loads per facility and per health care provider, at the ART clinics, were 58.86 and 4.91, respectively. Because actually less number of patients come to facilities at the weekends the workload was calculated only for the five working days. With the exception of one staff in Sabian health center, all staff working in ART clinics were trained on TB/HIV collaborative activities in general and IPT-implementation guideline in particular. *Implementation Guidelines for TB/HIV Collaborative activities in Ethiopia* was available in all facilities and all staffs were applying the proper eligibility criteria as per the guideline. *TB screening and IPT monitoring tool* was universally used with 24 incomplete forms found while data was collected from patient cards.

Pharmacies and laboratories were providing round-the-clock service throughout the year; however, opening hours did not necessarily indicate provision of HIV and TB related services as these services were usually provided during the formal 39 hours working hours during the five week days. For those patients who could not come in week days, facilities implemented a special arrangement for service provision during off-working hours and on week ends. IPT service had been discontinued for about two years due to unavailability of INH until November, 2009, which

was the time when the drug supply was re-instated. Since then, none of the facilities faced supply interruption with 100% (N 4) negative response to stock out in the past 90 days. Availability of INH 300mg and Pyridoxine by the time of visit was 100% in all facilities whereas that of INH100mg was 75% (N 4). As part of the comprehensive HIV care service, both INH and pyridoxine were provided free of charge (Table 3).

All facilities had functional laboratories and were staffed with qualified professionals by the time of visit. Dil Chora hospital was serving as a referral center for the health centers regarding all kinds of services including X-ray facility. The average number of laboratory professionals per facility was 6 (Facility range: 3 - 15). With an average number of 3 staff (Facility range: 2 - 7), the staffing was also good for the pharmacies.

ART service was well integrated with other services provided in the facilities. With the exception of one, 'intra-facility referral form' was used in all facilities to link patients with the relevant service point. In Melka Jebdu health center, linking clients with the next service point in-person contributed a lot in reducing the proportion of patients who might have left the facility without getting the service. The multi-disciplinary team (MDT) and the facility HIV committee (FHC) provided a strong base for service integration through their weekly and monthly meetings, respectively.

According to the head's of the facilities, acceptance of IPT among professionals was good. Adherence counseling was given to patients prior to IPT initiation although this study did not assess the details of the issues addressed. Patients' adherence was reportedly assessed during

each repeat visit through patient-provider discussion to identify barriers and make appropriate decisions. It was reported that peer-counselors were playing an important role in promoting adherence to both ARV drugs and INH.

A registration book to document individual level data on IPT was observed in all sites visited, which was found to have a varying degree of aggregation among facilities. However, compiled reports were unavailable in all visited sites (Table 3).

Table 3 Observed vailability of services in the facilities

Observations	**Status and Number of Facilities (N = 4)**	
	Yes	**No**
Drug available by time of visit		
INH300mg	4	0
INH100mg	3	1
Vitamin B6	4	0
Stock out of drugs in previous 90 days	0	4
Availability of counseling room		
ART clinic	4	0
Pharmacy	4	0
Functional laboratory	4	0
AFB microscopy done?	4	0
CXR available	1	3
Availability of reagents by time of visit		
Acid-alcohol	4	0
Stain	4	0
Stock out of reagents in previous 90 days	0	4
Guideline available*	4	0
Data on IPT available**	4	0

* Implementation guidelines for TB/HIV collaboration activities in Ethiopia

** Only individual level, but no aggregated, data on IPT.

The main challenges reported by the health facility managers were high professional turn over and inadequacy of refresher trainings. Two of the health facilities also reported a space problem.

5.2. Results of prevalence assessment

Record review showed that the aggregated prevalence for Dire Dawa city administration public health facilities was 37.29% (N 480) with the minimum of 20.29% for Sabian health center and a maximum of 83.33% at Melka Jebdu (Table 4).

Table 4 Prevalence of IPT in Dire Dawa city administration public health facilities

Name of facilities		# of PLHIV eligible for IPT	# of PLHIV for whom IPT was initiated	% PLHIV for whom IPT was initiated (IPT Prevalence)
	Legehare HC	47	15	31.91
	Dil Chora Hospital	313	128	40.89
	Sabian HC	69	14	20.29
	Melka Jebdu HC	6	5	83.33
	Dire Dawa HC	45	17	37.78
	Aggregated for Dire Dawa	**480**	**179**	**37.29**

5.3. Results of adherence assessment

The mean age of participants was 34.63 (SD 9.12) with a median age of 34 years, and 157 of them (65.97%) were females (Facility range: 43.37% - 100%). The majority of them (N 238, 67.6%) were on anti-retroviral therapy (ART), and 222 (N 238, 93.3%) of the participants were able to do their normal activities (Table 5).

Table 5 Summary of socio-demographic characteristics of study participants

Name of facility	# interviews	Average Age	% Female	% on ART	% able to do normal activity
Dil chora hospital	144	34.55	69.44	75.69	93.06
Sabian health center	41	34.59	73.17	34.15	100.00
Dire Dawa health center	31	34.42	48.39	80.65	90.32
Melka Jebdu health cent.	3	32.00	100.00	100.00	66.67
Legehare health center	19	36.16	47.37	52.63	89.47
Aggregated Mean for Dire Dawa	**48**	**34.63**	**65.97**	**67.65**	**93.28**
Maximum among facilities	144	36.20	100.00	100.00	100.00
Minimum among facilities	3	32.00	47.40	34.15	66.67

The average cost of transport was 3.02 birr (SD 13.72) with more than 89 percent of respondents pay 2 birr or less. The average times patients spent on travel and in the facility were 29 and 25 minutes, respectively, making the total time that the patient requires to get medical service less than one hour. Proper drug labeling was 73.46 percent (N 161) for the ARV drugs and 66.37 percent (N 238) for INH, which was poor when compared to the ideal 100 percent. Despite this, however, patient's knowledge with regards to drug dosage was very good with 160 (N 161, 99.8%) and 238 (N 238, 100%) of the participants reported to know how to take ARV drugs and INH, respectively (Table 6).

Table 6 Summary of patient care indicators

Name of facility	# interviews	% patients INH dispensed	% ARV drugs well labelled	% INH well labelled	% know dose of ARVs	% know dose of INH	Average cost to clinic(birr)	Average time to facility (minutes	Average time in facility(minutes)
Dil chora hospital	144	99.31	73.64	59.03	99.08	100.00	3.97	39.95	44.98
Sabian health center	41	97.56	92.86	100.00	100.00	100.00	1.59	26.34	27.68
Dire Dawa health center	31	100.00	60.00	58.06	100.00	100.00	1.74	38.39	25.65
Melka Jebdu health center	3	100.00	0.00	0.00	100.00	100.00	0.00	13.33	4.00
Legehare health center	19	100.00	100.00	73.68	100.00	100.00	1.47	25.26	21.47
Mean	**48**	**99.16**	**73.46**	**66.39**	**99.38**	**100.00**	**3.02**	**35.89**	**37.09**
Maximum	144	100.00	100.00	100.00	100.00	100.00	3.97	39.95	44.98
Minimum	3	97.56	0.00	0.00	99.08	100.00	0.00	13.33	4.00

Of the 238 participants, 52 (21.85%) missed one or more doses of INH in the past seven days. The aggregated self-reported complete adherence was 78.15 percent while self-reported adherence rate was 84.87 percent (N 238) (Table 7).

Table 7 Adherence rate

	Dil Chora hospital	**Sbian HC**	**Dire Dawa HC**	**Melka Jebdu HC**	**Legehare HC**	**Aggregated (Mean)**
Complete adherence	78.47	80.49	74.19	100	73.68	78.15
Adherence rate	84.03	82.93	87.10	100	89.47	84.86

5.4. Results on assessment of factors of adherence

Ten of the non-adherent (19.23%) missed all the seven doses with 70 percent of them reported the reason as being away from their home (Table 8 and 9).

Table 8 Frequency of INH doses missed in the previous seven days

Number of INH doses missed in the previous seven days			Name of health facility					Total
			Dil chora hospital	Sabian health center	Dire Dawa health center	Melka Jebdu health center	Legehare health center	
	0	Count	113	33	23	3	14	186
		% within Number of INH doses missed	60.8%	17.7%	12.4%	1.6%	7.5%	100.0%
		% with in facility	78.5%	80.5%	74.2%	100.0%	73.7%	78.2%
	1	Count	8	1	4	0	3	16
		% within Number of INH doses missed	50.0%	6.2%	25.0%	.0%	18.8%	100.0%
		% with in facility	5.6%	2.4%	12.9%	.0%	15.8%	6.7%
	2	Count	2	3	1	0	1	7
		% within Number of INH doses missed	28.6%	42.9%	14.3%	.0%	14.3%	100.0%
		% with in facility	1.4%	7.3%	3.2%	.0%	5.3%	2.9%
	3	Count	6	1	0	0	1	8
		% within Number of INH doses missed	75.0%	12.5%	.0%	.0%	12.5%	100.0%
		% with in facility	4.2%	2.4%	.0%	.0%	5.3%	3.4%
	4	Count	6	0	1	0	0	7
		% within Number of INH doses missed	85.7%	.0%	14.3%	.0%	.0%	100.0%
		% with in facility	4.2%	.0%	3.2%	.0%	.0%	2.9%
	5	Count	2	0	1	0	0	3
		% within Number of INH doses missed	66.7%	.0%	33.3%	.0%	.0%	100.0%
		% with in facility	1.4%	.0%	3.2%	.0%	.0%	1.3%
	6	Count	0	1	0	0	0	1
		% within Number of INH doses missed	.0%	100.0%	.0%	.0%	.0%	100.0%
		% with in facility	.0%	2.4%	.0%	.0%	.0%	.4%
	7	Count	7	2	1	0	0	10
		% within Number of INH doses missed	70.0%	20.0%	10.0%	.0%	.0%	100.0%
		% with in facility	4.9%	4.9%	3.2%	.0%	.0%	4.2%
	Total	Count	144	41	31	3	19	238
		% within Number of INH doses missed	60.5%	17.2%	13.0%	1.3%	8.0%	100.0%
		% with in facility	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

The most common reasons forwarded by participants for missing INH doses were being away from residential area, stock out at facilities, forgetfulness and running out of pills. These factors contributed about 75% (N 52) of the reported reasons for non-adherence (Table 8).

Table 9 Frequencies of reasons forwarded by patients for missing INH doses

Reasons for missing INH dose/s	Respondents	
	Number	%
Patient away from home	16	30.77
Forgot to take	11	21.15
Patient run out of pills	7	13.46
Drug out of stock at facility	5	9.62
Toxicity/side effect	3	5.76
Too ill to take pills	2	3.85
Fear of stigma/discrimination	2	3.85
Fasting	2	3.85
Drug shared with others	1	1.92
Too many pills/pill burden	1	1.92
Long waiting time	1	1.92
Missed appointment	1	1.92
Total	**52**	**100**

Socio-demographic variables and all the patient care indicators were not significantly associated with adherence. However, all participants with high level educational level (diploma holders and above) were 100 percent adherent to both ART and IPT. Of the females, 136 (N 157, 86%) were adherent to IPT compared to 66 of the males (N 81, 81.48%) showing that females were more adherent than males by almost 50 percent. The Adherence rate was also better for those on ART as compared to those who were on pre-ART by more than 60 percent. However, when the other factors were adjusted, the odds of adherence considerably decline for both females and those on ART as compared to their corresponding crude values (Table 9).

Table 10 Association of factors with adherence

Factors	Adherent (N 238)		Crude OR (95% CI)	Adjusted OR (95% CI)
	Yes	No		
Sex				
Male	66	15	1	1
Female	136	21	1.47 (0.71-3.03)	0.72 (0.31-1.66)
Patient status				
Pre-ART	62	15	1	1
On ART	140	21	1.61 (0.78-3.34)	0.49 (0.22-1.09)
Age				
18 – 24	22	5	1	1
25 – 34	78	16	0.90 (0.30-2.74)	0.77 (0.24-2.55)
35 and above	102	15	0.65 (0.21-1.97)	0.51 (0.15-1.72)
Level of education				
Illiterate	63	8	1	1
Primary education	95	24	1.99 (0.84-4.71)	2.20 (0.87-5.54)
Secondary education	32	4	0.98 (0.28-3.52)	0.87 (0.23-3.30)
Cost of transport in birr (home to clinic)				
0 – 2	180	33	1	1
3 – 10	17	3	0.96 (0.27-3.47)	0.62 (0.10-3.95)
Travel time in minutes (home to clinic)				
0 – 30	136	23	1	1
31 – 60	58	10	1.02 (0.46-2.28)	1.05 (0.41-2.65)
61 – 120	5	3	3.55 (0.79-15.87)	6.21 (0.73-52.69)
Waiting time in minutes (in clinic)				
0 – 30	135	21	1	1
31 – 60	43	10	1.50 (0.65-3.42)	2.24 (0.88-5.72)
61 – 120	19	5	1.69 (0.57-5.02)	2.98 (0.87-10.21)

The calculated crude and adjusted odds ratio were zero for those patients with high level of education (diploma holders and above), who paid more that 10 birr for transport, who spent more than 120 minutes traveling and those who spent more than 120 minutes in the facility.

6. Discussion

6.1. Health facilities' organizational capacity

In general terms, the study found out that the health facilities were organized in such a way that they were able to provide quality health services. The exceptional strength observed in all facilities was the strong service integration through intra-facility referral system and the strong coordinated leadership provided by the multi-disciplinary team (MDT) and facility HIV committee (FHC). Specific to services provided at the ART clinics, professional staff availability and mix was good with at least one medical doctor/health officer assigned full time supported by trained nurse/s. However, the need to recruit and/or train more staff should be planned to mitigate the high professional turn over that prevails currently.

The calculated work load for the facilities was 4.91 patients/professional/day, which was lower than a documented 16 patients/professional/day reported by a national study conducted in Ethiopia (23). Though results show a relatively lower work load in Dire Dawa, the huge difference among facilities (Facility range: 0.98 - 58.86) should not be overlooked. For instance, with 58.86 patients daily visit per professional at Dil Chora hospital, one would not expect an adequate consultation time for quality service provision.

Working environment was also satisfactory with a chance for relevant trainings, availability of isolated counseling rooms, appropriate guidelines, drugs, laboratory services and a team-oriented attitude. Informal data collected from patients and information from heads of facilities suggested that the patient-provider information was very good. The role of peer counselors in tracing defaulters and in promoting adherence to treatment was another plus to the efforts of the facilities.

Some of the weaknesses observed were poor documentation with regards to IPT service and absence of or incomplete 'TB screening and IPT monitoring tool' for some cases. The patient level data on IPT, registered in a separate log book, was not compiled in such a way that simplified information extraction for easy understanding and monitoring. The newly implemented HMIS, which was designed to create a harmonized filing system, was also another challenge that facilities faced, especially in tracing records of patients who were enrolled in HIV chronic care program; totally, 20 patient cards were not found in the five facilities.

6.2. Prevalence of IPT

Despite the observed enabling factors, however, the prevalence of IPT was very low (37.29%). This figure is of course by much higher than the global 0.06% IPT prevalence reported by WHO in 2005 (5). However, it was in contrast with the information from facility managers who, with no exception, reported that IPT was provided to the majority, if not all, of the eligible. This perceived high coverage by the facility managers might have emerged because none of the facilities had a compiled data (report) on IPT service.

Though the study did not try to identify the reasons in detail, one of the possible reasons for this low level of IPT coverage might be the weak facility level supervision and mentoring. This argument might be supported by the observed immediate corrective action that the staff of Legehare health center took by starting to put almost all eligible individuals on IPT following the first day of data collection at the facility. Another possible reason is the difficulty in ruling out active TB by the existing diagnostic facility and existing staff capacity. However, the above mentioned reasons might have contributed to the reported low prevalence but should not be taken as the only reasons by any means.

6.3. Level of adherence

The adherence rate determined by this study (84.87%) was higher than results of other studies done in South Africa (72%) and Thailand (67.5%) (7, 9). However, it was lower than reported 88.2 percent adherence by a study conducted in America (8) (Table 8). A number of factors might explain the difference: the difference in the assessment methodologies, the cut off points, the study setting, the time of the study and others.

The study in America (8), which employed a number of different methods, indicated that self-report overestimates adherence as compared to more objective methods of evaluation such as urine test and electronic lead monitor. The South African study, for instance, determined adherence through a more objective method (urine test), which was able to detect INH metabolites in the urine. In Thailand pill count was used to measure adherence. In general, the non-adherence rate in Dire Dawa (15.13%) was with in the range of 11.8 to 37 percent rates that were reported by other studies (6 - 9).

6.4. Factors of adherence

Of the three groups of possible factors that would affect adherence (Figure 1), the results showed that the contributions of health service and community level factors to non-adherence were minimal. Long waiting time (health service factor) and fear of stigma/discrimination (community level factor) were given as reason for not taking INH doses by only 1 (1.92%) and 2 (3.85%) patients, respectively. The stock out at facilities was reported by five respondents (N 52, 9.62%) was not supported by the findings of the facility observations, which informed that the drugs were continuously available since November, 2008.

The most frequently mentioned reasons were traveling away from residential area, forgetfulness and running out of pills, which are individual factors and have a lot to do with attitude and self discipline. This was in contrast with reported good pre and post treatment adherence counseling by facility managers because the mentioned reasons might possibly be explained by lack of clear understanding of treatment and self–discipline. The difference between the adherence rates to IPT (84.87%) and to that of ARV drugs (90.69) could also be due to patients' varying perception about the risks associated with missing the two groups of drugs. While further investigations are required for better understanding of the underlying causes, these factors are indications that inform the need for reviewing the adherence counseling strategies and take appropriate actions for the future.

Though there was no statistically significant association between the level of education and adherence, all participants with higher education (diploma holders and above) were 100 percent adherent to both ART and IPT. The study did not determine if this difference in adherence arose

from relatively better understanding among the educated or whether education affected standard of living, which in turn promoted adherence among the better offs. Though this needs further investigation, one can still consider the probability of designing a different approach of counseling that addresses specific requirements of different categories of the community, and if possible that of individuals.

Demographic and other factors such as travel time, time in facility and transportation cost, were not found to be significantly associated with adherence. Though not significant, the observed better adherence of females (OR 1.47) was also reported by a study in Thailand (9) while another study in America did not find a significant effect of sex on adherence (8). One study (9) suggests that visiting patients improves adherence, and if so, facilities should design and implement a strategy to work very closely and collaboratively with the existing peer counselors, who are believed to access clients at a relative ease.

Finally, this study involved professionals who were responsible for implementation of IPT and improve adherence one way or the other. The fact that all the data collectors were health professionals who were working in the assessed facilities and that health facility managers were part of the study contributed a lot in helping them understand the reality with regards to IPT service and adherence. It is the author's firm belief that this would encourage facilities to maximize their effort and achieve better results in the future as exemplified by the action taken by Legehare health center.

7. Conclusions

Health facilities were well positioned with adequate capacity to provide IPT services for those who seek the treatment. Health facility managers reported satisfactory service coverage and commendable achievements in adherence. However, there was a huge gap between the facility managers' perception and the actual results of the study; this was observed regarding both IPT service coverage and adherence, which were low.

Patient related factors were the major reasons for missing doses among the non-adherent constituting more than 65 percent of all causes. Health facility and community level factors were not among the common reasons forwarded for non-adherence. None of the socio-demographic variables, patient status and patient care indicators was found to be significantly associated with level of adherence.

In conclusion, the findings clearly show that increasing IPT coverage and improving adherence require much more than quality guidelines, adequate organizational capacity and availing drugs. As indicated in the national TB/HIV implementation guidelines, the study found out that attitude and follow-up are still the main challenges for better service utilization.

8. Recommendations

This study indicated the need to design and implement effective strategies to increase IPT service coverage and improve adherence. The following actions are recommended to be considered by relevant parties:

- Examine facility specific barriers to IPT initiation and take appropriate corrective actions;
- Design and implement a strategy for periodic review of IPT service provision and adherence; utilizing the existing functional structures (MDT, FHC) whenever feasible;
- Improve patient records' filing system; design and implement a mechanism that would enable to proper documentation and retrieval of IPT service related data at facility and health bureau level;
- Strengthen the existing adherence-counseling system to guarantee high adherence rate in such a way that addresses the reasons for non-adherence that are identified by this study;

9. Strengths of the study

One of the strengths of the study was that it involved facility managers and health professionals working in the targeted facilities, which contributed a lot for the quality of the data. It also helped the facilities' staff to get first hand information about the implementation status of IPT in their respective facilities. On the other hand, this study was among the few, if any, which documented current situation with regards to IPT service provision in Ethiopia.

10.Limitations of the study

One of the limitations of this study was that it did not include the private sector in Dire Dawa that makes generalization difficult. The other limitation was that data on adherence was collected by self report and there is a probability for recall and social desirability biases. One other possible limitation was that the status of those individuals whose patient records were not retrieved and those for whom TB screening form was not completed was not known, which might have affected the results.

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12.Appendix

Appendix I: Consent form

Consent Form

This study is for partial fulfillment of a post-graduate program jointly provided by Addis Continental Institute of Public Health and University of Gondar. The objective is to determine the level of use of IPT and the rate of adherence among users in Dire Dawa. It will also try to identify the possible determinants of adherence to IPT. Identifying these issues would help to design and implement an intervention to expand the service and improve adherence.

In this study we will be collecting data from service providers and patients who are taking INH for preventive therapy.

Since you are taking INH, we would like to ask you some questions. The information you will be giving us will be used only for study purposes and your names and specific addresses are not required. The information generated will be disclosed in totality and all your personal information will be confidentially treated.

To fill this questionnaire it will take from 10 to 15 minutes. You have all the right to refuse to answer to any of the questions and to withdraw at any time.

If you would like to participate, will you sign here please?

Principal investigator: _____ Participant: _____

Appendix II: የተሳትፎ ስምምነት ማረጋገጫ

ይህ ጥናት በአዲስ ኮንቲነንታል ኢንስቲቲዩት ኦፍ ፐፕሊክ ኸልዝ እና በሳንደር ዩኒቨርሲቲ በጋራ ለሚሰጥ የድህረ-ምረቃ ስልጠና ማሟያ የሚደረግ ነው። የጥናቱ አላማም በአሁኑ ወቅት የቲቢ መከላከያ መድሃኒት በመጠቀም ላይ የሚገኙ ሰዎችን ብዛት ለማወቅና የአጠቃቀማቸውን ሁኔታ ለመዳሰስ ነው። በተጨማሪም፣ መድሃኒቱን በአግባቡ ለመጠቀም የሚያግዙ መረጃዎችም ይሰበሰባሉ። የጥናቱ ውጤትም፣ የተጠቃሚዎችን ቁጥር ለማሳደግና አጠቃቀሙንም ለማሻሻል የሚያስችሉ ስልቶችን ለመንደፍና ለመተግበር ያግዛል።

ለዚህ ጥናት ከጤና ባለሙያዎችና የቲቢ መከላከያ መድሃኒቱን በመውሰድ ላይ ካሉ ተጠቃሚዎች መረጃ ይሰበሰባል። እርስዎም የዚህ መድሃኒት ተጠቃሚ በመሆንዎ ጥቂት ጥያቄዎች ልንጠይቅዎ እንፈልጋለን። የሚሰጡን መረጃ ለዚህ ጥናት ብቻ የሚውል ሲሆን፣ ስምዎትና የሚኖሩበት አድራ-ዎትን አንመዘግብም። የጥናቱም ወጤት በአጠቃላይ የሚገለጽ ሲሆን ማንነትዎትን የሚያሳውቅ መረጃ በድብቅ የሚያዝ ይሆናል።

ይህንን መጠይቅ ለመመላት ከአስር እስከ አስራ አምስት ደቂቃ ይፈጃል። መመለስ የማይፈልጉትን ማንኛውንም ጥያቄ ያለመመለስና በፈለጉት ወቅት ቃለ-ምልልሱን የማቆም መብት አለዎት።

መረጃ ሊሰጡን ፈቃደኛ ከሆኑ እባክዎ እዚህ ጋር ይፈርሙ፣

የጥናቱ መሪ፣ ---------- የጥናቱ ተሳታፊ፣ ----------

Appendix II: Data Collection instruments

Tool 1: In-depth Interview Guide with the Head of the Facility

Name of facility: _____

Name of the respondent: _____

Name of the interviewer: _____

Date: _____

Prior to the interview, relevant official documents should be presented including the support letter from ACIPH/UoG and the permission from the Dire Dawa city administration health bureau. The principal investigator should describe to the respondent about the purpose of the study, the duration, the activities to be undertaken and all other relevant information; it is only possible to proceed with the data collection after securing permission from the head. Most importantly, the investigator should inform the respondent about the de-briefing on the study findings and secure a suitable date and place accordingly.

Expected interview period: 45-60 minutes

Interview with the head of the facility

1. **Organization:** I would like for us to discuss the general set-up of your organization. Are there any problems? Do you have suggestions how to resolve problems and how to, maintain/improve performance?

2. **Staff:** Now let's discuss the staffing situation in your ART clinic. *Probes*: Are there enough number of persons? How is the mix between professions? How do you see the acceptance of

IPT by the staff? Are there any problems? Do you have suggestions how to resolve the problems? How to maintain good performance? What kind of training activities?

3. **IPT service:** What do you think about the coverage of IPT in your facility? Do you think the guidelines are well communicated to your staff? How/why? What are the major challenges with regards to initiating IPT? What do you think shall be done?

4. **Supply of drugs:** What is your INH supply situation? ***Probes:*** Do you ever get stock outs? What is the reason? How do you solve it? Are there barriers to make these drugs available? What do you suggest shall be done?

5. **Patients:** How do patients perceive services here? *Probes:* Are they satisfied with opening hours? With staff? With laboratory services? Are there complaints about access? About number of days for each drug delivery? What can be done to improve adherence?

6. **Lab resources:** What TB investigations are performed at the lab? Do you always have reagents and other necessary things? Well-trained staff? Any other problems?

7. **Integration:** Do you offer the following services at your facility? HCT, ANC, PMTCT, TB, or others? If "Yes" How does the integration function? Strengths and weaknesses?

8. **General:** What are the strongest features of your facility? What are the most important barriers to better performance? Do you see any problems other than what we have discussed?

Tool 2: Checklist for Facility Observations

1. Organization

Is the ART clinic integrated with any of the following?

- HCT Yes _____ No _____
- ANC/ PMTCT Yes _____ No _____
- TB clinic Yes _____ No _____
- Other Yes _____ No _____

2. Working Hours

Days	**# of Hours ART clinic**	**# of Hours Laboratory**	**# of Hours Pharmacy**
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
Total hours/Week			

3. Staff

3.1. Is there a TB/HIV focal person in the facility? Yes _____ No _____

3.2. How many staff are working in ART clinic, laboratory and pharmacy in a normal day?

Unit/Department	**# of professional**
ART clinic	
Laboratory	
Pharmacy	
Total	

4. Supply and dispensing of drugs

4.1. How many staff in the pharmacy by the day of visit? _____

Could I see your medical store and stock records for INH and Pyridoxine? Fill in the following table.

No.	Item	Present by time of visit (Y/N)	Stock out in the last 3 months (90 days) (Y/N)
1	Isoniazid 300 mg tablet		
2	Isoniazid 100 mg tablet		
3	Pyridoxine tablet		
	Total		

4.2. Average time to dispense? _____ (Need to observe 10 dispensing episodes and get average time)

5. Patients

5.1. How many patients are visiting the ART clinic? _____ (Patient registration for the day)

5.2. How many patients are visiting the pharmacy (ART)? _____ (Dispensing registration for the day)

5.3. Private space for counseling in ART clinic? Yes _____ No _____

5.4. Private space for counseling in ART pharmacy? Yes _____ No _____

6. Laboratory resources

6.1. Is it functional? (not at all, partially, fully) _____

6.2. Do you have TB microscopy manual?

Yes: ___ No: ___

Laboratory workload:

Description	**# in the past one year**
# of (new) TB suspects examined	
# of follow-up patients examined	
Total	

Note: Specify the period for the data. _____

Fill the following table:

No.	**Item**	**Present by time of visit (Y/N)**	**Stock out in the last 3 months (90 days) (Y/N)**
1	Acid		
2	Alcohols		
3	Stains		
	Total		

7. IPT service data

7.1. Do you have the national 'implementation guidelines for TB/HIV collaborative activities in Ethiopia' 2008 edition? (Check for presence)

Yes: ___ No: ___

7.2. Do you have written/documented criteria to determine eligibility for IPT?

Yes: ___ No: ___

7.3. Do you have documented data on the number of people who are on IPT?

Yes: ___ No: ___

Can I see it please?

Note: Write the name of the register/document used for this purpose. _____

Fill in the following table:

# of PLHIV enrolled in the past 12 months	# of PLHIV eligible for IPT	# of PLHIV for whom IPT was initiated	# of PLHIV who received INH

Note: If there is no documented report, go through patient records for those PLHIV who are enrolled only during the past one year.

8. General

Overall impression of the facility

_____

_____

Tool 3: Patient Exit Interview Tool

Tool 3: Patient Exit Interview Instrument

Patient exit interview

Name of facility: _____ **Date:**_____

Interviewer: _____

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Pt #	Age (Yr)	Gender (M/F)	Client Status (P/A)	Level of Education (1 to 5)	Normal activity (Y/N)	Cost home to clinic (ETB)	Time Home to clinic (in mins)	Time in Clinic today (in mins)	Months on ART	Months on IPT	ARV regimen dispensed (Y/N)	INH dispensed (Y/N)	Pyridoxine dispensed (Y/N)	ARV drugs well labelled (Y/N)
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														
11														
12														
13														
14														
15														
16														
17														
18														
19														
20														

Key:
Level of Education: 1=Illiterate, 2=primary, 3=Secondary, 4= Diploma, 5= first degree and above.
Client Status: P= Pre-ART client, A= client on ART
Y= Yes
N= No
ETB= Ethiopian Birr
Cost: Use both birr and cents; i.e. 2.6 to indicate 2 birr and 60 cents
Months on ART/IPT: Write only completed months
If pyridoxine is not prescribed, put NA in columns N and Q to indicate Not Applicable.
If the answer for any of the columns L, M and N is No (N), put NA in columns O, P and Q accordingly.

P	Q	R	S	T	U	V	W	X
INH well labelled (Y/N)	Vt. B6 well labelled (Y/N)	pt knows how to take ARVs (Y/N)	pt knows how to take INH (Y/N)	# Doses ARVs missed in last 7 days	# Doses INH missed in last 7 days	Reason for Missing INH doses (Code 1-17)	If "Other" then specify reason for missing doses:	Codes for column V
								1 = Toxicity-Sde effect
								2= Shared with others
								3=Forgot
								4= Felt Better
								5= Too ill
								6= Stigma/discrimination
								7=Drug out of stock (HF)
								8=Patient ran out of
								pills or lost them
								9= Do not know dose
								10=Alcohol
								11=Depression
								12=Start other treatment
								13= Fasting
								14=Away from home
								15 = too many pills
								16= Long waiting time
								17= Missed appointment
								Specify for 'Others'